HFA-305

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

99 APR 20 P2:18

Jean A. Shepherd
Director, Risk Management/Safety
Terrebonne General Medical Center
8166 Main Street
P.O. Box 6037
Houma, Louisiana 70361

APR 19 1999

Re: Docket No. 99P-0233

Dear Ms. Shepherd:

This responds to your citizen petition dated December 10, 1998, in which Terrebonne General Medical Center requests a temporary variance from compliance with the Performance Standard for Electrode Lead Wires and Patient Cables, which became effective on January 1, 1999. Your petition has been clarified twice, once in a letter dated December 31, 1998, written by Mr. Steve Williams, Director of BioMedical Engineering, and again in a letter dated January 29,1999, written by Ms. Phyllis Peoples, R.N., MSN, Associate Director of Nursing. The request is for a temporary variance for 61 of the 165 beds in your facility based on the economic feasibility of purchasing compliant cables and lead wires for a monitoring system scheduled for replacement by mid-1999. Your request includes a corresponding commitment to implement a tagging program for the noncompliant devices, which may provide some additional measure of patient safety. FDA is granting your variance request.

The petition concerns the following devices that are itemized in the January 29, 1999, letter from Ms. Peoples of your facility:

Telemetry Monitor, Model ZB12PA, 21 units
Telemetry Monitor, Model ZB860PA, 8 units
Telemetry Monitor, Model ZB312PA, 13 units
Hardwire Monitor, Model ZB655OB, 10 units
Portable Monitor, Model OEC6105A, 2 units
Hardwire Monitor, Model ZB654PB, 7 units

The devices for which you request a variance are included among the ten specified devices for which electrode lead wires

99P-0233

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and patient cables are required to comply with the performance standard. On August 3, 1998, FDA issued a letter to all user facilities, notifying them of their responsibility for compliance with the performance standard, and extending the compliance time frame until January 1, 1999, for electrode lead wires and patient cables used with those ten devices. Your approved variance further extends that date to July 31, 1999, at which time all electrode lead wires and patient cables used with your telemetry monitoring systems will be expected to be in compliance with the performance standard.

I trust that this response fully addresses your concerns. If additional information is required, please contact Kent Berthold in our Office of Compliance at (301) 594-4648.

Sincerely yours,

for Elizabeth D. Jacobson, Ph.D.
Acting Director
Center for Devices and
Radiological Health